

## **DRAFT PROGRAMME**

### **Microbial Agents in Animal Cell Substrates: An Update on Testing & Methods**

**Location: NIH, Natcher Auditorium  
Bethesda MD**

**Date: 20-21 April 2009**

This workshop will review current developments in the detection of both endogenous and exogenous microbial contaminants of animal cells used for the production of biologicals, and is co-sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) and the International Association for Biologicals (IABS) with input from the World Health Organization (WHO). Speakers include experts from WHO, public health agencies, pharmaceutical and biopharmaceutical industries, regulatory and control agencies, and research institutes. The overall objective of the meeting is to review past testing experience, data on current testing technology, and to consider evolving strategies and emerging testing technologies. The output of the meeting is expected to be a consensus on the issues and recommendations on microbial agent testing of animal cell substrates.

Following the workshop, a WHO Study Group will convene to continue discussion of the revision of the current WHO Requirements on animal cell substrates, taking into account the output of the workshop.

Participants for this workshop will include those working or interested in the following areas: biologicals research, quality control, quality assurance, regulation, standards, and clinical development.

Organizing Committee: I. Knezevic (WHO), R. Sheets (NIAID/DAIDS & VRC), J. Petricciani (IABS), S Kim Grossman (NIAID/DMID), G. Stacey (NIBSC)

#### **Day 1            Monday April 20, 2009**

8:00 - 9:00 am        Registration and refreshments

#### **SESSION I: Background to the revision of the current WHO guidance document on cell substrates**

(Moderator: John Petricciani, IABS)

9:00 - 9:10 am        Welcome Remarks, John Petricciani, IABS, Chair, WHO Study Group

9:10 – 9:40 am        Ivana Knezevic, WHO Recommendations for the use of cell substrates: key issues in the revision

**SESSION II: Traditional Tests under Consideration**

(Moderator: Rebecca Sheets, NIAID)

9:40 – 9:50 am	Moderator's introduction
9:50 - 10:20 am	Andrew Kerr, Detection of Adventitious Viruses in Biologicals (A Rare Occurrence)
10:20 – 10:50 am	Coffee Break
10:50 – 11:20 am	Jens-Peter Gregersen, Novartis, Qualitative-comparative and quantitative models to assess adventitious agents risks for a cell culture derived influenza vaccine
11:20 – 11:50	Paul Duncan, Merck, Molecular detection methods for adventitious and endogenous agents in the context of a systematic approach to vaccine cell substrate and culture characterization - Merck's practical experience
11:50 – 1:15 pm	Lunch (on your own)
1:15 – 1:45 pm	TBD
1:45 – 3:15 pm	Panel Discussion & Conclusion of the Session by the Moderator
3:15 – 3:45 pm	Tea Break

**Session III: Evolving Strategies**

(Moderator: Sonnie Kim Grossman, NIAID/John Petricciani, IABS)

3:45 – 4:15 pm	Sonnie Kim Grossman, DMID, Moderator's introduction and NIAID initiatives & recent technological developments
4:15 – 4:45 pm	Arifa S. Khan, CBER, Evaluation of latent viruses in novel vaccine cell substrates by chemical induction
4:45 – 5:15 pm	Keith Peden, CBER, Quantitative in vitro and in vivo assays to assess the biological activity of residual DNA in viral vaccines

**Day 2 Tuesday April 21, 2009****Session III (cont.):**

8:00 – 8:30 am	Refreshments
8:30 – 8:35 am	Call to Order by Session III moderator
8:35 – 9:05 am	Carol Marcus-Sekura, BASI, Systematic review of bovine/porcine tests
9:05 – 9:35 am	David Asher, CBER, Attempts to Infect Cell Substrates Used in the Manufacture of Biologics with the Agents of Bovine Spongiform Encephalopathy and Creutzfeldt-Jakob Disease
9:35 - 10:05 am	Vladimir Chizhikov, CBER, New approaches for improving the detection and identification of mycoplasma agents in cell substrates
10:05 - 10:30 am	Coffee Break

10:30 - 12:00 pm     Panel Discussion & Conclusion of the Session by the Moderator

12:00 - 1:30 pm     LUNCH (on your own)

**SESSION IV:        Emerging Test Technology**

(Moderator:   Glyn Stacey, NIBSC)

1:30 – 1:40 pm       Moderator's Introduction

1:40 – 2:10 pm       Ranga Sampath, IBIS, New and Rapid Methods to Detect Viral Contaminants in Cell Substrates

2:10 – 2:40 pm       John Sherlock, Applied Biosystems, The Use of TaqMan Arrays for standardized, accurate & sensitive qPCR detection of adventitious agents

2:40 – 3:10 pm       Michael J. Hantman, Charles River Laboratories, Detection of Mycoplasma/Acholeplasma Contamination by Amplification of Specific Nucleic Acids and Fluorescent Probe Technology

3:10 – 3:40 pm       David Onions, BioReliance, New Methods of Adventitious Agent Detection: mass spectrometry, arrays, and massively parallel sequencing

3:40 – 4:00 pm       Tea Break

4:00 – 5:15 pm       Panel discussion & Conclusion of the Session by the Moderator

5:15 – 5:30 pm       Final conclusions and recommendations

5:30 pm                ADJOURN